REMARKS

In a final Office Action mailed March 25, 2003, the Examiner rejected claims 1 and 21-24 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim subject matter which the Applicant regards as the invention.

The Applicants have amended claims 1, 21-22 and added claim 25 to more clearly define the present invention.

Support for these amendments is found in the original specification. Specifically, in claim 1 the pocket is now defined as being sized and shaped to capture a predetermined volume of fluid sample and this structure is described on page 6 lines 1-6 of the original specification. In addition, the pocket is defined as extending outwardly from the casing and this is clear from the drawings particularly Figures 1, 2 and 5. The pocket structure extending from the casing enables the pocket to capture and contain the predetermined volume of fluid sample.

In addition, the feed element is defined as including at least one feed inlet through a planar surface for providing fluid communication between the sample pad and the pocket. The feed element is disposed with sufficient pressure between the generally planar surface the sample pad in order to control a rate of fluid sample release from the pocket. Support for this amendment is found on page 10, lines 28 to page 11, line 1. This amendment is made to specifically overcome the Examiner's rejection of claim 1

under 35 USC 112, second paragraph by defining the structure which connects the metering means and the testing assembly and the communication between the feed inlets with the sample.

Claim 21 has been amended to define the feed inlets as providing control release of fluid in the pocket to the feed element. Similar amendment is made to claim 22.

The Examiner's rejection of claim 23 under 35 USC 112, second paragraph is traversed in view of the fact that claim 23 depends from claim 21 and the chamber is claimed as defining the pocket which is sized and shaped to capture and contain a predetermined volume of fluid sample.

The indefiniteness requirement of 35 USC 112 is essentially a requirement for precision and definiteness of claimed language, so that the claims make clear what subject matter they encompass and thus what the patent precludes others from doing. In re Spiller, 182 USPQ 614, 621 (CCPA 1974). See also in re Johnson and Farnham, 194 USPQ 187, 193 (CCPA 1997).

The test for indefiniteness under 35 USC 112, second paragraph, is whether one of ordinary skill in the art would understand what is claimed in light of the specification. See Seattle Box Company v. Industrial Crating and Packing, 221 USPQ 568, 574 (Fed. Cir. 1194) and Burlington Industries, Inc. v. Quigg, 229 USPQ 916, 920 (D.C. 1986).

Claim 23, and for that matter claims 1 and 21-22, must be read in light of the specification. With regard to claim 23 the relationship of the chambers clearly set forth on page 6 - lines 8-21. Clearly, as set forth in specification the means for supporting the casing on a generally horizontal surface with the pocket disposed in a spaced apart relationship with generally horizontal surface allows a laboratory technician to dip or submerge a device in a collection cup in order to obtain the appropriate volume of fluid to run the test and thereafter immediately place the device aside directly on a countertop without causing any wet contact between the device and the countertop.

In view of the present amendment to the claims, the Applicants respectfully request the Examiner to withdraw the rejection of claims 1 and 21-24 under 35 USC 112, second paragraph.

Claims 1 and 22-24 have been rejected by the Examiner under 35 USC 102(b) as being clearly anticipated by U.S. 6,203,757 to Lu, et al. or U.S. 5,656,503 to May, et al.

The Applicants submit that anticipation under 35 USC 102(b) is established only when a single prior art referenced discloses, each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc. 221 USPQ 385 (Fed. Cir. 1984).

Applying this criteria with regard to Lu, et al., it is clear that there is no teaching whatsoever of a pocket

which extends outwardly from a casing for capturing and containing a predetermined volume of fluid sample.

The opening referred to by the character reference 24 in Figure 2 of the Lu, et al. reference is structurally formed only to receive droplets of fluid as indicated in the Figure and according provides no outwardly extending structure for capturing fluid. Accordingly, the claims as amended are not anticipated by the Lu, et al. reference and the Examiner is respectfully requested to withdraw the rejection of the claims under 35 USC 102(b) on the basis of the Lu, et al. reference.

With reference to May, et al., it is clear that there is no structure similar to the feed element of the present invention which is disposed with sufficient pressure between a generally planar surface and a sample pad in order to control a rate of fluid sample release from a pocket.

The May, et al. reference teaches a receptacle 202 in which fluid sample rises by a capillary action through the test strip 206 and conveys the label reagent from zone 208 to the two circular zones 209 and 210, see column 11, lines 32-36. In view of the fact that there is no teaching or suggestion in May, et al. of the feed element, structure in accordance with the present invention which functions to control the rate of fluid sample from the receptacle 202 by application of pressure, the Applicants submit that a rejection under 35 USC 102(b) on the basis of May, et al. is not sustainable and respectfully request the Examiner to withdraw the rejection of the claims based upon May, et al.

Claim 21 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Lu, et al. or May, et al. in view of U.S. 5,976,896 to Cipkowski.

The Examiner relies on Cipkowski for teaching a test device having multiple feed inlets to simultaneously test for multiple analytes which saves time and money for the lab. While Cipkowski may teach multiple inlets, it certainly provides no teaching or suggestion of structure similar to that of the present invention which includes a pocket sized and shape to capture a predetermined volume of fluid which projects outwardly from a casing, nor does it provide any teaching or suggestion of a feed element which is disposed with sufficient pressure between a generally planar surface and a sample pad in order to control a rate of fluid sample release from a pocket containing the fluid sample.

Thus, the Applicants submit that the Examiner has not made a prima facie case of obviousness with the combination of Lu, et al., May, et al. and Cipkowski under 35 USC 103(a). Therefore, the Applicants respectfully requests the Examiner to withdraw the rejection of claim 21 under 35 USC 103(a).

Claim 25 has been added to define the test device in accordance with the present invention as including grip means positioned on the casing for facilitating the dipping of the device into a fluid container in order to fill the pocket with fluid sample. Support for this added claim may be found on page 13, lines 15-20. This structure is

related to the pocket and the casing by way of facilitating the use of the device. No such structure is taught or suggested by any other references cited by the Examiner.

In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,

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